


Amendments to the claims:

This listing of claims will replace all prior versions and listing of claims in the application:

Claim 1 (currently amended): A stable liquid formulation of a biologically therapeutically active protein useful for aerosol delivery to the respiratory tract of a patient in need of treatment comprising:

- (a) a carrier liquid ~~comprising~~ consisting essentially of from about 10% v/v to from about 100% ~~V/V~~ v/v water and from about 0% to from about 90% ~~V/V~~ v/v of an organic liquid;
- (b) a biologically effective amount of a said protein suspended or dissolved in said carrier liquid; and
- (c) a stabilizing effective amount of a derivatized carbohydrate stabilizing agent suspended or dissolved in said carrier liquid;

 ~~wherein said derivatized carbohydrate is selected from the group consisting of C8-trehalose, C16-trehalose, C8-glycopyranoside and C12-glucopyranoside~~ wherein said derivatized carbohydrate comprises a sugar moiety selected from the group consisting of trehalose, sucrose, glucose, maltose, and galactose modified by the addition of at least one alkyl or alkenyl hydrocarbon group attached to said sugar moiety at carbon 1, 2, 3, 4, 5, or 6 and wherein said hydrocarbon group contains about 6 to 18 carbon atoms which may be straight chain or branched chain and wherein said therapeutically active protein is not an enzyme.

Claim 2 (currently amended): A stable formulation ~~suspension~~ according to claim 1 wherein said formulation contains from about 0.1% w/v to about 5.0% w/v ~~V/V~~ of a pharmaceutically acceptable excipient.

Claim 3 (currently amended): A stable formulation according to claim 1 wherein said biologically therapeutically active protein is selected from the group comprising enzymes, antibodies, antigens, hormones and cytokines.

Claim 4 (original): A stable formulation according to claim 3 wherein said therapeutically active protein is a hormone.

Claim 5 (original): A stable formulation according to claim 4 wherein said therapeutically active protein is insulin.

Claim 6 (original): A stable formulation according to claim 3 wherein said therapeutically active protein is a cytokine.

Claim 7 (original): A stable formulation according to claim 6 wherein said therapeutically active protein is Factor VIII.

Claim 8 (currently amended): A stable formulation according to claim 1 wherein said carrier liquid contains from about 20% v/v to from about 100% v/v water ~~V/V~~.

Claim 9 (currently amended): A stable formulation according to claim 8 wherein said carrier liquid comprises about 50% v/v water and about 50% v/v organic solvent.

Claim 10 (currently amended): A stable formulation according to claim 1 wherein said organic liquid is selected from the group consisting of ethanol, isopropyl alcohol, butanol, isobutanol, perfluorocarbons, glycerol, polyethylene glycol, propylene glycol, or combinations thereof.

Claim 11 (currently amended): A stable formulation according to claim 10 wherein said organic liquid is selected from the group consisting of ethanol, glycerol, polyethylene glycol, propylene glycol, or combinations thereof.

Claim 12. (previously presented): A stable formulation according to claim 1 wherein said derivatized carbohydrate is selected from the group consisting of C8-trehalose and C8-glycopyranoside.

Claim 13 (original): A stable formulation according to claim 1 wherein said protein is suspended in the carrier liquid.

Claim 14 (original): A stable formulation according to claim 13 wherein the particle size of said protein in suspension is from about 0.01 μ to about 10.0 μ .

Claim 15 (original): A stable formulation according to claim 14 wherein the particle size of said protein in suspension is from about 5.0 μ to about 10.0 μ .

Claim 16 (original): A stable formulation according to claim 15 wherein the particle size of said protein in suspension is from about 0.01 μ to about 3.0 μ .

Claim 17 (original): A stable formulation according to claim 2 wherein said formulation contains from about 0.1% to about 5.0% of a pharmaceutically acceptable excipient.

Claim 18 (original): A stable formulation according to claim 1 wherein said protein is dissolved in the carrier liquid.

Claim 19 (currently amended): A stable formulation according to claim 18 wherein said formulation contains from about 0.1% w/v to about 5.0% w/v of a pharmaceutically acceptable excipient.


20. (currently amended): A stable liquid formulation of a biologically therapeutically active protein useful for aerosol delivery to the respiratory tract of a patient in need of treatment comprising:

- (a) a carrier liquid which consists essentially of is from about 20% v/v to from about 30% ~~V/V~~ v/v water and from about 70% v/v to from about 80% ~~V/V~~ v/v of ethanol;
- (b) a biologically effective amount of a said protein suspended or dissolved in said carrier liquid; and
- (c) a stabilizing effective amount of a derivatized carbohydrate stabilizing agent elected from the group consisting of C8-trehalose, C16-trehalose, C8-glucopyranoside and C12-glucopyranoside;

wherein said derivatized carbohydrate comprises a sugar moiety selected from the group consisting of trehalose, sucrose, glucose, maltose, and galactose modified by the addition of at least one alkyl or alkenyl hydrocarbon group attached to said sugar moiety at carbon 1, 2, 3, 4, 5, or 6 and wherein said hydrocarbon group contains about 6 to 18 carbon atoms which may be straight chain or branched chain and wherein said therapeutically active protein is not an enzyme.

Claim 21 (canceled)

Claim 22 (currently amended): A stable liquid formulation of a biologically therapeutically active protein useful for aerosol delivery to the respiratory tract of a patient in need of treatment comprising:

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- (a) a carrier liquid consisting essentially of from about 10% v/v to from about 100% v/v ~~v/v~~ water and from about 0% to from about 90% v/v ~~v/v~~ of an organic liquid;
 - (b) a biologically effective amount of a protein suspended or dissolved in said carrier liquid; and
 - (c) a stabilizing effective amount of a derivatized carbohydrate stabilizing agent suspended or dissolved in said carrier liquid;

wherein said derivatized carbohydrate comprises a sugar moiety selected from the group consisting of trehalose, sucrose, glucose, maltose, and galactose modified by the addition of at least one alkyl or alkenyl hydrocarbon group attached to said sugar moiety at carbon 1, 2, 3, 4, 5, or 6 and wherein said hydrocarbon group contains about 6 to 18 carbon atoms which may be straight chain or branched chain and wherein said protein is not an enzyme.
